REMARKS

Claims 1-19 and 21-30 are pending in the application. Claims 1, 16, 19 and 21-22 have been amended. Claim 16 has been amended to correct a typographical error. New claims 23-30 have been added. Claim 20 has been cancelled. Applicant reserves the right to pursue the original claims and other claims in this and in other applications.

Claims 1-9, 11, 14, 15 and 18-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 4,873,975 to Walsh et al. (Walsh) in view of U.S. Patent 4,892,098 to Sauer (Sauer). The rejection is respectfully traversed.

Claim 1, as amended, recites "each of the inner and outer sleeves is made separable or operable so that they can be removed without severing the first or second hallow organ after anastomosis formation has been completed." Amended claim 1 moreover recites "[the] outer circumference of the entire end portion of the inner sleeve over which the first hollow organ lies is smooth."

Similarly, amended claim 19 recites that "each of said inner and outer sleeves is constructed so as to be openable or separable in a fashion that permits removal of said sleeves from said first and second hollow organs without severing said first or second hollow organ after completion of said anastomoses." Moreover, amended claim 19 recites that the "inner sleeve comprises a substantially tubular end portion" and that the "outer circumference of said substantially tubular end portion is smooth."

As reflected in paragraph [0005] of the present specification, the claimed invention relates to a device for anastomosis that can be removed from the patient's body after completion of anastomoses. Moreover, as described in paragraphs [0007] and [0010] (see e.g., page 5, lines 8-14) of the present specification, the claimed invention seeks to provide a gentle, yet secure and permanent connection of hollow organs using electrocoagulation.

Contrary to the removable electrocoagulative anastomosis device of the invention of claims 1 and 19, Walsh teaches an anastomosis device that is retained in the patient's body, holding the hollow organs against one another by spring pressure and thus allowing the hollow organs to

graft by natural biological processes (cf. Walsh Fig. 24 and its corresponding description at col. 11, lines 8-9 and 29-34). The Office Action states that the connector of Walsh is viewed as being a removeable because it could be removed at any time (*i.e.* upon death or resecting). Office Action at 3. However, the Office Action misses the point of the present invention. The device of the present invention is removed upon completion of anastomses not at a later time after the patient has died or when a physician is re-entering the body at another point in time. Walsh fails to teach or suggest removing the connector at the time the anastomosis device is first used by the physician, not at a later time.

Walsh does not seek to provide a device that is removable immediately after completion of anastomoses. Accordingly, as compared to the present invention, the embodiment shown in Figs. 9A and 9B of Walsh is disadvantageous in two respects. First, connection cylinder 12 is not separable or openable and thus does not allow removal after completion of anastomoses without severing hollow organ 92. Second, even if the connection cylinder 12 were to be made of openable or separable components, the provision of flange 28 would hinder release of the connection cylinder since the diameter of flange 28 is larger than the diameter of the interface of spring clip 14 and connection cylinder 12, the flange 28 has a larger diameter than the diameter of the electrocoagulatire, weld-like anastomoses between the first and second hollow organs and would thus be trapped therein. Since the present invention as recited in independent claims 1 and 19 provides for an end portion having a smooth outer circumference, the end portion cannot become trapped by the anastomotic "weld." This feature, in combination with the feature wherein the inner and outer sleeves are made separable or openable, allows for removal of the sleeves in a manner unforeseen by Walsh, specifically in and without severing the hollow organs.

Sauer fails to cure the Walsh deficiencies. Having regard for the explicit aim of Walsh, Applicant still earnestly questions whether the person skilled in the art would find the alleged motivation in Sauer to modify the device of Walsh to comprise a separable inner sleeve. In this respect, Applicant notes that, unless the invention of Walsh were modified to provide a swift form of anastomosis, *e.g.*, electrocoagulative anastomosis, modification of the inner sleeve to be separable would be without practical utility; that is, it would entail the undesirable risk of additional

surgery for removing the anastomosis device after the natural healing process is completed. Yet, as noted above, the device of Walsh would require significant modification to be suitable for electrocoagulative anastomosis. Indeed, Applicant firmly believes that such modification would contradict the essence of the Walsh teachings. Accordingly, the Walsh and Sauer combination is improper as Sauer teaches away from use with Walsh.

Accordingly, Walsh and Sauer, either alone or in combination, fail to teach "each of the inner and outer sleeves is made separable or operable so that they can be removed without severing the first or second hallow organ after anastomosis formation has been completed," as recited in claim 1 and "each of said inner and outer sleeves is constructed so as to be openable or separable in a fashion that permits removal of said sleeves from said first and second hollow organs without severing said first or second hollow organ after completion of said anastomoses," as recited in claim 19. Claims 2-9, 11, 14, 15 and 18 depend from claim 1 and claims 21-22 dependent from claim 19 are allowable along with claims 1 and 19, respectively, for at least the foregoing reasons. The rejection should be withdrawn and the claims allowed.

Claim 10 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Walsh in view of Sauer and U.S. Patent 4,470,415 to Wozniak (Wozniak). The rejection is respectfully traversed.

Claim 10 depends from claim 1 and is allowable over the Walsh and Sauer combination for at least the reasons set forth above. Wozniak, cited as allegedly teach plastic connectors, fails to cure the above noted deficiencies. As such, claim 10 is allowable over the cited combination. The rejection should be withdrawn and the claim allowed.

Claims 12, 13, 16, 17 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Walsh in view of Sauer and U.S. Patent 5,649,937 to Bito et al. (Bito). The rejection is respectfully traversed. Claims 12, 13, 16 and 17 depend from claim 1 and claim 22 dependents from claim 19 and are allowable over the Walsh and Sauer combination for at least the reasons set forth above. Bito, cited as allegedly teaching a sensor, fails to cure the above noted

deficiencies. As such, claims 12, 13, 16,17 and 22 are allowable over the cited combination. The rejection should be withdrawn and the claims allowed.

New claims 23-28 depend from claim 19 and are allowable for at least the reasons mentioned above. New claims 29 and 30 each claim that the inner and outer sleeves are constructed so as to be openable or separable in a fashion that permits removal of said sleeves from said first and second hollow organs without severing said first or second hollow organ after completion of said anastomoses. In addition, claims 29 and 30 recite an electrically conductive contact surface that extends in a longitudinal direction of the inner/outer sleeve for a length that is less than a length of the inner/outer sleeve in said longitudinal direction, the electrically conductive contact surface and the inner/outer sleeve being of different materials. These features allow for precise and efficient formation of anastomoses without the complications associated with devices left in the patient upon completion of the operation. The cited prior art does not teach these features. Accordingly, Applicant believes new claims 23-30 are allowable.

In view of the above, Applicant believes the pending application is in condition for allowance. Favorable action on the merits is earnestly solicited.

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Respectfully submitted,

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